



Australian Government

Department of Health and Aged Care  
Therapeutic Goods Administration

# Australian Register of Therapeutic Goods Certificate

Issued to

**GAIA Medical Pty Ltd**

for approval to supply

## **GAIA Medical Pty Ltd - Viscopaste PB7 - Dressing, wound-nonadherent, permeable**

<b>ARTG Identifier</b>	411214
<b>ARTG Start Date</b>	26/06/2023
<b>Product Category</b>	Medical Device Included Class III
<b>GMDN</b>	46855
<b>GMDN Term</b>	Dressing, wound-nonadherent, permeable
<b>Intended Purpose</b>	Intended Purpose is To assist the management of venous leg ulcers. Where venous insufficiency exists the paste bandage should be used under graduated compression therapy. For the management of chronic eczema/dermatitis where occlusion is indicated.

Manufacturer Details	Address	Certificate number(s)
Evolan Pharma AB	Svardvagen 19 , Danderyd , 182-33 Sweden	DV-2022-MC-15062-1

### **ARTG Standard Conditions**

The above Medical Device Included Class III has been entered on the Register subject to the following conditions:

- The inclusion of the kind of device in the ARTG is subject to compliance with all conditions placed or imposed on the ARTG entry. Refer Part 4-5, Division 2 (Conditions) of the Therapeutic Goods Act 1989 and Part 5, Division 5.2 (Conditions) of the Therapeutic Goods (Medical Devices) Regulations 2002 for relevant information.
- Breaching conditions of the inclusion related to the device of the kind may lead to suspension or cancellation of the ARTG entry; may be a criminal offence; and civil penalties may apply.

### **Products Covered by This Entry**

#### **1. Viscopaste PB7 - Dressing, wound-nonadherent, permeable**

<b>Functional Description</b>	Viscopaste is a general purpose first-line treatment for wet and dry leg ulcers. Viscopaste provides topical treatment. It provides a moist wound healing environment over a leg ulcer, helps to reduce skin irritation and soothes and protects surrounding skin. It will not dry out in use. Viscopaste bandages soothe and protect the skin and are easily removed. Where venous insufficiency exists, Viscopaste may be used under graduated compression bandaging.
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### **Variant Information**

Description	Range
Nil variant (as 1 device)	0

### **Product Specific Conditions**

No specific conditions have been recorded against this entry.

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